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February 12, 2019

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Test Substance:

8EHQ-18-21621

Generic Name: Haloalkane

This letter is to inform you of the results of an inhalation study with the above-referenced test substance. This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, because it is information in which EPA may have an interest.

The objective of this study was to evaluate the acute inhalation toxicity of the test substance when administered as a single, 4-hour nose-only exposure to rats.

The test substance was administered to 3 groups of 5 male and 5 female Sprague Dawley rats via nose-only inhalation exposure at target exposure concentration of 30, 75, and 100 ppm test substance; achieved mean analyzed vapor concentrations were 29, 75, and 130 ppm, respectively. Males and females were exposed at the same time.

Mortality, clinical observations (including immediately following exposure and 1-2 hours post exposure), body weights, and body weight changes were evaluated over a 14-day post-exposure observation period. Necropsies were conducted on all animals.

Fractional mortality was 0/10, 8/10, and 10/10 in the 29, 75, and 130 ppm groups, respectively. All deaths occurred on the day of exposure (Day 1). All animals in the 130 ppm group and 1 male and 1 female in the 75 ppm group died during exposure. The remaining 4 males and 2 females in the 75 ppm group died following exposure on Day 1. All males and females in the 29 ppm group and the remaining 2 females in the 75 ppm group survived to study termination (Day 15).

Two males and 2 females in the 75 ppm group had tremors during exposure prior to death. The remaining test substance-related clinical observations were limited to the 75 ppm group females and consisted of abnormal gait, decreased activity, increased vocalization, and/or cold to touch following exposure on Day 1. The 2 females in the 75 ppm group that survived to study termination had decreased feces output 1 to 4 days following exposure. These females also had red and or yellow fur staining on various body surfaces for up to 4 days following exposure. These females were considered clinically normal by Day 3 or 6. No clinical observations were noted for the 29 ppm group males and females.

In surviving animals, no statistically significant body weight gain or body weight losses from Day 1 to Day 2 were observed. All surviving animals surpassed their initial (Day 1) body weight by Day 15.

For the animals that died on study, failure of the lungs to collapse was observed for 2/5 and 5/5 males and 3/3 and 3/5 females in the 75 and 130 ppm groups, respectively. Other macroscopic findings for these animals included foci (usually dark red) in the lungs and dark red discoloration of the liver. In addition, red matting of the nasal, buccal, and/or ocular areas and/or frothy material accumulation in the trachea (130 ppm only) were noted for some of these animals. At the Day 15 scheduled necropsy, no macroscopic findings were observed.

Based on the results of this study, the test substance 4-hour LC50 was 66 ppm when male and female Crl:CD(SD) rats were exposed to a vapor of the test substance during a single, nose-only exposure.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Substantiation of our claim of confidentiality is included herewith as **Attachment 1**. Please contact me if you have any questions about this submission or need further clarification.

Sincerely,

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Attachment 1

Entire Substantiation Claimed as Confidential Business Information